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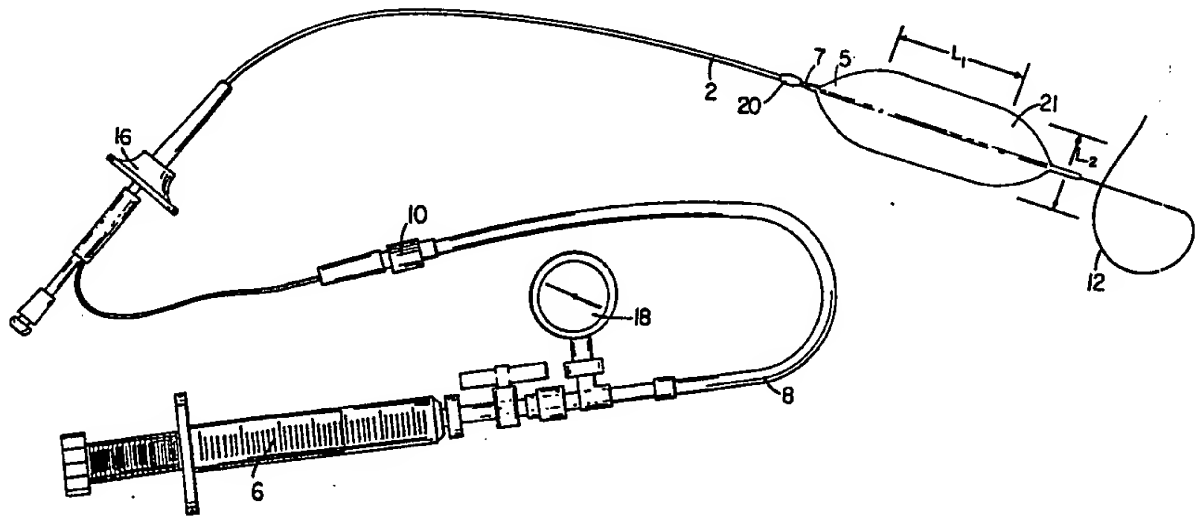

(57) Abstract

A dilation balloon (4) for medical use formed of a major amount of a crystallizable polymer such as high molecular weight polyethylene terephthalate with an intrinsic viscosity greater than about 0.7, and a relatively minor amount of an additive polymer that interrupts the crystalline structure of the crystalline polymer in the final product. The final product is a blend that when formed into a balloon (4), exhibits advantageous properties of softness, i.e., compliance and a low folded profile, yet achieves high hoop stress and consequently high burst pressures. The balloon in the deflated state will thus yield when challenged by the wall of the lumen yet can be inflated to high pressure for performing the dilatation

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additive is about 20% or less of the polymer blend. The additive is between about 5 to 10% of the polymer blend.

Particular embodiments may also include one or more of the following. The crystalline polymer is high molecular weight PET. The PET has an intrinsic viscosity greater than of about 0.7 or greater. The balloon is adapted for dilatation of the prostate. The balloon wall has a thickness of about 0.0015 inch or less. The balloon has a burst pressure of more than 6 atmosphere. The balloon has a burst pressure of 4 to 8 atmosphere. The balloon has a hoop strength of greater than about 36,000 lbs. The balloon exhibits enhanced compliance over PET of about 25% or more with decreased hoop stress of about 10% or less. The polymer blend is free inflated to form the balloon.

In another aspect, the invention features a catheter for dilatation. The catheter includes a catheter shaft carrying for inflation at its distal end, a dilation balloon. The balloon is composed of a polymer blend including a major amount of a relatively noncompliant polymer and a minor amount of a relatively compliant additive polymer, the blend resulting in a balloon of enhanced compliance.

In another aspect the invention features a method for forming a medical balloon. The method includes preparing a polymer blend of a major amount of a crystalline polymer with a relatively minor amount of an additive polymer that interrupts the crystalline structure of the crystalline polymer and forming the blend into a balloon resulting in enhanced compliance.

Particular embodiments may include one or more of the following. The preparing includes blending a crystallizable polymer with the additive, and crystallizing the polymer. The forming includes free

connector 10 to a balloon lumen 12 terminating in an inflation port (not shown) within the balloon 4. The catheter shaft 2 carrying the balloon 4 may be tracked over a guidewire 12 which passes through an additional lumen (not shown) within the shaft 2 and is introduced through a collar 16. The apparatus further includes a pressure gauge 18 for monitoring the inflation pressure and a positioning nodule 20 which permits precise placement with transrectal digital control so that dilation is not extended through the external sphincter and eliminates the need for cystoscopy or fluoroscopy. Retraction collar 16 permits hand traction for maintaining precise positioning during dilation.

Referring now to Fig. 2, the balloon is shown in the deflated position, prior to introduction into the body lumen. As illustrated, the balloon 4 is wrapped by wing-folding about the catheter shaft 2 and has a profile of L_3, about 0.182 - 0.195 inch. The purpose of the wrapping and folding of the balloon is to minimize the deflated profile so that the catheter may be passed through the body lumen to the desired point of treatment. As shown, in the deflated condition, the balloon includes a series of folds 20 that extend to radial diameters (L_3), greater than the outer diameter of the catheter body. These folds 20 will typically engage the inner walls of the body lumen as the catheter is torqued to the position of treatment.

The balloon is composed predominantly of a blend of crystallizeable resin and an additive that interrupts the crystalline network of the crystalline resin in the final product. When the blend is formed into a balloon, the balloon exhibits advantageous properties of softness, i.e., compliance and a low folded profile, yet achieves high h op stress and consequently high burst pressures. The balloon in the deflated state will thus yield when

reinforce the crystalline structure of the crystalline polymer.

In particular embodiments, the balloon is composed of a minor amount of heterogeneous, preblended, polyolefin (e.g. polyethylene) and a polyester (e.g. PET); the preblend is then blended with a relatively high molecular weight PET. Suitable polyolefins and polyesters for forming the preblend and methods for blending incompatible polymers are known and are discussed in U.S. Patent No. 4,444,817 entitled *"Process for Making Laminar Articles of Polyolefins and Condensation Polymer"*, by Subramanian, the entire contents of which are hereby incorporated by reference. The polyolefin is, for example, polyethylene, polypropylene, polybutylene or copolymers of these materials and may be of high, medium or low density. The condensation polymers may be a polyamide, or polyester such as PET or polycarbonates. Typically, a compatiblizer is used. Suitable compatiblizers include alkylcarboxyl-substituted polyolefins, e.g., the polymerization product of an α-olefin with an olefinic monomer having acid groups or a polyethylene and copolymer of ethylene and at least one α-olefin of 3-8 carbon atoms such as polypropylene, which might be formed by grafting. Compatibilizers are further discussed in U.S. 4,444,817, supra. To form the preblend, the polymer particles may be mixed by high shear techniques such as micronized dispersion and by other techniques discussed in U.S. 4,444,817.

The balloon may be formed by free inflation of the polymer blend to crystallize the crystallizeable polymer and form a biaxially oriented polymer, as discussed in U.S. Patent No. 4,963,313 entitled, "Balloon Catheter" by Noddin et al., the entire contents of which are hereby

polymer. For example, in a particular embodiment employing PET and polyethylene, the PET, because it is crystalline, contributes the strength and high burst properties but is, itself, a relatively stiff, non-compliant material that upon deflation exhibits a relatively traumatic profile to the lining of the body lumen under treatment. Polyolefin contributes properties of improved softness or compliance such that the balloon may yield (e.g., deflect or compress) when challenged by the wall of a body lumen by interrupting the crystalline structure of the PET. The blend of these components does not, however, greatly reduce the strength of the balloon.

Examples

Example I

In formulating the polymer blend less than about 20% by weight of Selar PT resin is mixed with bottle grade PET (*Clear Tuf*® 8006, available from GoodYear). The components are mixed mechanically by conventional methods such as with an extruder. Balloons may be formed by free inflation as discussed in U.S. 4,963,313, incorporated supra. A tube of the polymer blend of which the balloon is to be composed is provided. A portion of the tube is crystallized to render it dimensionally stable under heated conditions. The tube is immersed in a heated bath of glycerin at a drawing temperature (e.g., 120°C). Both the crystallized region and a short portion of the amorphous region of the tube are fully immersed in the tube. The portion of the tube out of the bath is gripped by a clamp and the crystallized portion of the tube submerged in the bath is gripped by an additional, movable clamp. After a suitable duration of immersion to insure that the resin reaches the temperature of the bath, the movable clamp is moved downwardly a predetermined distance, at a draw rate, e.g., 0.3 inch

140-160°C, e.g., 150°C for one minute. The balloon may be assembled upon a suitable catheter.

Example II

Balloons having a length of 5 cm and wall thickness as given in Table I, line 4 were formed as discussed above in Example I. In the tests below, the balloon is assembled on a mandrel system which enables inflation and measurement of burst pressure and inflation diameters. Referring to Table I below and Figs. 3-5, the strength of balloons measured by the burst and hoop stress, as well as the compliance of the balloons as measured indirectly by the inflated outer diameter and inflated length are compared for balloons formed, respectively from 100% PET, 90% PET and 10% Selar PT, and 80% PET and 20% Selar PT. Burst pressure (Fig. 3, Table 1, line 6) was measured by inflation of balloons to bursting; hoop stress at failure (Fig. 4, Table 1, line 7) was calculated using hoop stress equations as well-known; compliance was measured in several forms: the outer diameter (OD at 30 psi) was measured (Table 1, line 9); the percent change of inflated outer diameter at 60 psi and 30 psi (Fig. 5, Table 1, line 10) and 90 psi and 30 psi (Fig. 5, Table 1, line 11) were measured as well as the percentage change in inflated length at 60 psi and 30 psi (Fig. 5, Table 1, line 12) and 90 psi and 30 psi (Fig. 5, Table 1, line 13). Table 1 also indicates in columns G, H, and I the significance of the differences in values tested between the various balloons.

In Fig. 5 and Table 1, lines 9-13, the compliance of the balloons is compared by indirect measurements. Referring now to Fig. 5, the compliance of the balloons by measurement of the percent change in inflation outer diameter and length at different pressures (60 psi versus 30 psi and 90 psi versus 30 psi) as in Table 1, lines 10-13 is shown in bar graphical form. In each case, the balloons formed according to the invention, including an additive, show greater percentage inflated size than a balloon formed from 100% PET. The percentage increase for the balloons employing the additives was at least about 25% higher compared to the balloons formed from 100% PET. (For example, referring to Table 1, line 10, the change in percentage increase for the 90%/10% PET/Selar balloon compared to the 100% PET balloon is 1.3% which is a percentage increase for the additive balloon of 50% over the 100% PET balloon.) Referring to Table 1, line 9, the inflation diameter of the balloons at 30 psi are given. The balloons including an additive show greater inflation diameter than balloons formed from 100% PET.

As the results in the table and graphs indicate, for balloons employing a blend of crystalline polymer and an additive, significant improvements in compliance where observed while only small reductions in strength resulted, compared to the balloon formed from 100% PET.

Other Embodiments

It will be understood that balloons of varying sizes and for varying applications may be formed according to the invention, as discussed. For example, balloons of inflated diameter in the range of 2 to 8 mm, having burst pressures in the range of up to 12 atmospheres, may be formed. Other applications may employ balloons of varying sizes and strengths, as required. For example, a balloon according to the

CLAIMS

1. An inflatable dilation balloon for medical use, comprising:

a polymer blend including a major amount of a crystalline polymer, and

a relatively minor amount of an additive polymer that interrupts the crystalline structure of said crystalline polymer resulting in enhanced compliance.

2. The balloon of claim 1 wherein said additive is incompatible with said crystalline polymer.

3. The balloon of claim 2 wherein said additive forms domains within said blend.

4. The balloon of claim 1 wherein said additive is compatible with said crystalline polymer.

5. The balloon of claim 1 wherein said additive is an amorphous polymer.

6. The balloon of claim 5 wherein said additive is a polyolefin.

7. The balloon of claim 6 wherein said additive is polyethylene.

8. The balloon of claim 1 wherein said additive is a crystalline polymer.

9. The balloon of claim 8 wherein said additive is a liquid-crystal polyester material.

22. The balloon of claim 1 wherein said balloon exhibits enhanced compliance over PET of about 25% or more with decreased hoop stress of about 10% or less.

23. The balloon of claim 1 wherein said polymer blend is free inflated to form said balloon.

24. A catheter for dilatation, comprising:
a catheter shaft carrying for inflation at its distal end, a dilation balloon,
said balloon composed of a polymer blend including a major amount of a relatively noncompliant polymer and
a minor amount of a relatively compliant additive polymer, said blend resulting in a balloon of enhanced compliance.

25. A method for forming a medical balloon, comprising,
preparing a polymer blend of a major amount of a crystalline polymer with a relatively minor amount of an additive polymer that interrupts the crystalline structure of said crystalline polymer, and
forming said blend into a balloon resulting enhanced in compliance.

26. The method of claim 25 wherein said preparing comprises blending a crystallizable polymer with said additive, and
crystallizing said polymer.

27. The method of claim 26 wherein said forming comprises free inflation of said polymer blend.

AMENDED CLAIMS

[received by the International Bureau on 17 March 1992 (17.03.92); original claims 1,2,4,12,24,25,29 amended; original claim 13 cancelled; other claims unchanged but renumbered (4 pages)]

1. An inflatable medical dilation balloon comprising:

a polymer blend including a predominant amount of a crystalline polymer, and

a compliance enhancing amount of an additive polymer sufficient to interrupt the crystalline structure of said crystalline polymer, said amount being about 20% or less of the polymer blend.

2. The balloon of claim 1 wherein said additive is immiscible with said crystalline polymer.

3. The balloon of claim 2 wherein said additive forms domains within said blend.

4. The balloon of claim 1 wherein said additive is miscible with said crystalline polymer.

5. The balloon of claim 1 wherein said additive is an amorphous polymer.

6. The balloon of claim 5 wherein said additive is a polyolefin.

7. The balloon of claim 6 wherein said additive is polyethylene.

8. The balloon of claim 1 wherein said additive is a crystalline polymer.

9. The balloon of claim 8 wherein said additive is a liquid-crystal polyester material.

20. The ball on of claim 1 wherein said balloon has a hoop strength of greater than about 36,000 lbs.

21. The balloon of claim 1 wherein said balloon exhibits enhanced compliance over PET of about 25% or more with decreased hoop stress of about 10% or less.

22. The balloon of claim 1 wherein said polymer blend is free inflated to form said balloon.

23. A dilatation catheter comprising:

a catheter shaft carrying a dilatation balloon which can be inflated at its distal end,

said balloon composed of a polymer blend including a predominant amount of a crystalline polymer and

a compliance enhancing amount of an additive polymer sufficient to interrupt the crystalline structure of said crystalline polymer, said amount being about 20% or less of the polymer blend.

24. A method for forming a medical balloon, comprising,

preparing a polymer blend of a predominant amount of a crystalline polymer with a compliance enhancing amount of an additive polymer sufficient to interrupt the crystalline structure of said crystalline polymer, said amount being about 20% or less of the polymer blend, and

forming said blend into a balloon.

25. The method of claim 24 wherein said preparing comprises blending a crystallizable polymer with said additive, and

crystallizing said polymer.

26. The method of claim 25 wherein said forming comprises free inflation of said polymer blend.

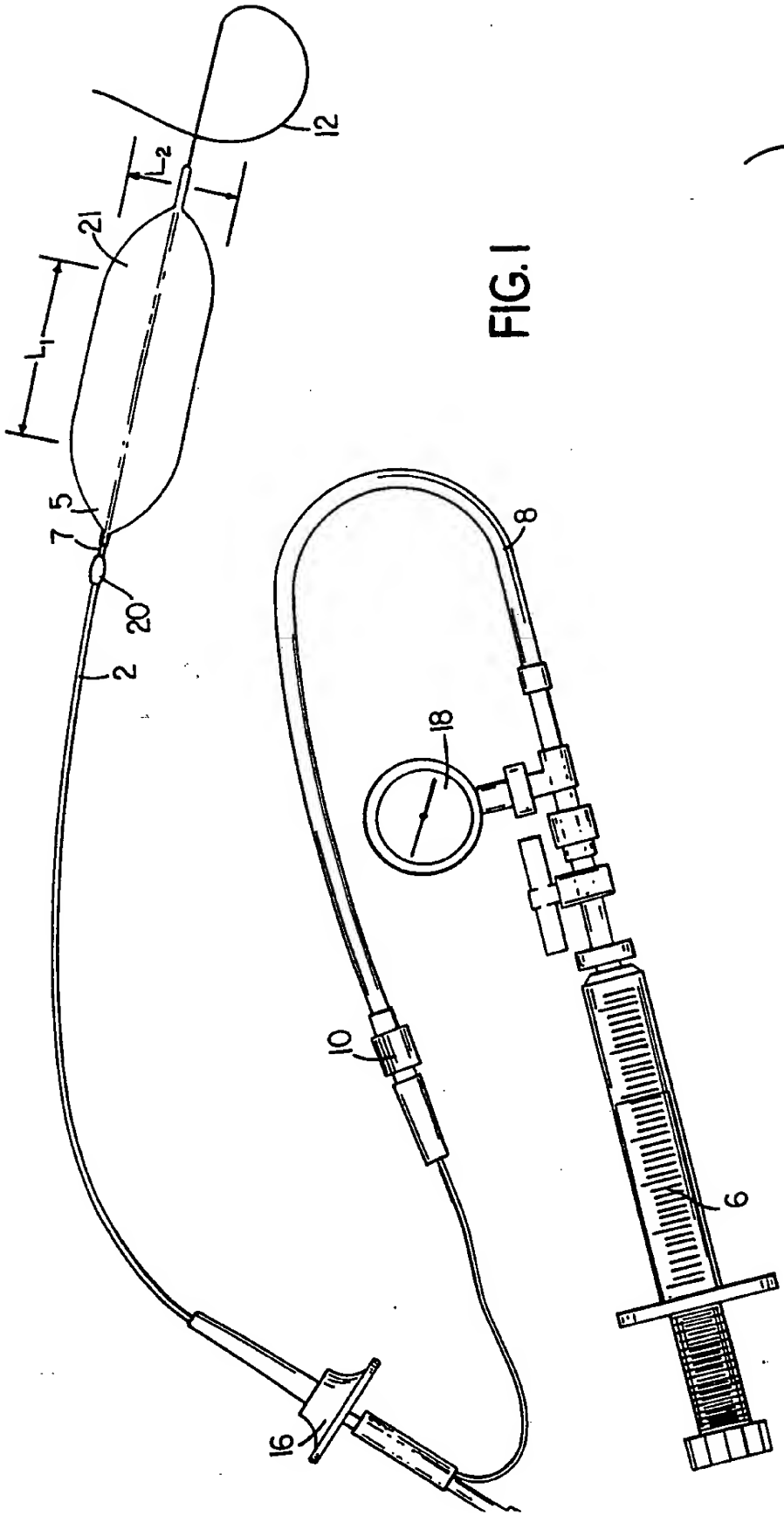

FIG. 1

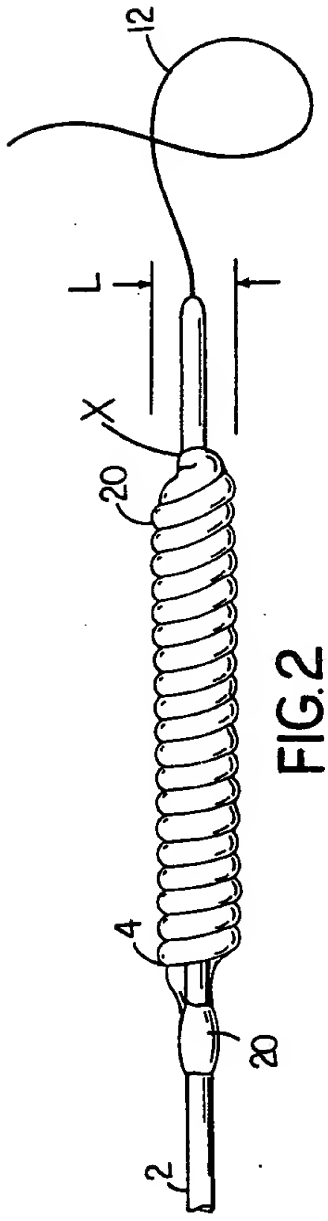

FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/08374

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61M 29/00
U.S. CL.: 604/96

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	604/96; 264/515; 428/36

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X Y	US, A, 4,946,743 (WINTER) 07 August 1990, See entire document.	1-23 24-29
X Y	US, A, 4,254,774 (BORETOS) 10 March 1981, See entire document.	1-10,17,18, 23-29 11-16,19-22

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